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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,751	03/07/2002	Paul Hebeisen	20858	1027

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER

BERNHARDT, EMILY B.

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/02/2003

b

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/092,751	Applicant(s) HEBEISEN et al.
	Examiner Emily Bernhardt	Art Unit 1624
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
Period for Reply		
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status		
1) <input type="checkbox"/> Responsive to communication(s) filed on _____.		
2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-34</u> is/are pending in the application.		
4a) Of the above, claim(s) <u>33</u> is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>1-32 and 34</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input checked="" type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1: <input checked="" type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152).		
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>2,4 & 5</u>		
6) <input type="checkbox"/> Other: _____		

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Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-32 and 34, drawn to compounds and compositions, classified in class 544, subclass 344; class 514 subclass 249.
- II. Claim 33, drawn to processes for making alkylated compounds of I, classified in class 544, subclass 349.

The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case more than one type of alkylation step can be used to make only some of the final products. Additionally, other processes in the prior art exist to make instant compounds of Group I.

During a telephone conversation with Mr. Tramaloni on 5/7/02 a provisional election was made without traverse to prosecute the invention of I, claims 1-32 and 34. Affirmation of this election must be made by applicant in replying to this

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Office action. Claim 33 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

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Complete revision of the content of the abstract is required on a separate sheet.

The abstract of the disclosure is objected to because the structural makeup of instant compounds is not depicted. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: On p.7 ‘aryl’ is defined as described “above” but appears to be defined “below”, namely on p.8. Appropriate correction is required.

Claims 1-14,16,18,20,22,24,26,28,30, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation of “solvates” in main claim 1 and claims dependent thereon is unclear as to intended scope since only hydrates are ever identified in the specification as suitable. Generally, not all solvents can form solvates with all compounds.

2. Recitation of a pharmaceutically acceptable ester” is of indeterminate scope. While specification 2 classes of esters for the COOH group, optionally present in some of the variables, the definition is open-ended and thus not clear what other moieties present can be further esterified.

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Claims 1-14,16,18,20,22,24,26,28,30 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. Generic, subgeneric and several species claims which embrace any solvate are nonenabled since generally not all solvents can form solvates with all compounds.

There is no process enabling such a scope in the specification .

2. Other than thienyl particularly exemplified as one of R1-R4 embraced in the R variable , the specification does not reasonably provide enablement for the scope of heterocycles as broadly defined in the specification which appears throughout the R1-R4 variables. There is no reasonable basis for assuming that the myriad of het-substituted compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement

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as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition. Thus given the breadth of the claims, the level of unpredictability in the art directed to receptor binding which is known to be structure-sensitive and the lack of direction (i.e. working examples) provided as to what other rings, ring systems as heterocyclic (at various locations) might work, this rejection is being applied.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams (WO'753, cited by applicants). The WO publication employs some of instant compounds as precursors to hexahydro analogs. See tetrahydro derivatives described in egs. 2, 4-6, 12 and 13.

Claims 1, 8-10 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Bos (EP'863, cited by applicants). The EP publication describes some of the instant compounds for use in a variety of pharmaceutical applications including obesity, migraine and many others as set forth on p.2. See examples 1-15.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7, 11-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bos in view of Adams. Compounds embraced by these claims are structurally very similar to those compounds in Bos discussed in the above 102 rejection. Compounds such as in claim 11 and 12 differ only in nature or placement of substituent(s) on phenyl ring, i.e. at 7,8, or 9-positions vs 6-position particularly required in claim 12. Note however that Bos permits R1/R2 at all available positions on the benzene ring and with the same type of substitution as herein included halo, alkyl, haloalkyl. Remaining claims rejected herein require Me groups at R5 or R6. While Bos does not particularly teach alkyl at 1 and/or 4-positions, Adams does for very similar compounds having the same uses as in Bos. See R1/R3 definitions therein.

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Additionally, there is case law regarding H vs Me on otherwise old compounds that has decided H vs Me in otherwise old compounds is not considered patentable absent evidence of superior,unexpected results. Note In re Wood 199 USPQ 137; In re Lohr 137 USPQ 548; In re Fauque 121 USPQ 425. Thus it would have been obvious to one skilled in the art at the time the invention was made to expect compounds claimed herein that are variously substituted on the benzene ring and/or methylated on the piperazine ring carbons to also possess the uses taught by the art in view of the equivalency teaching and close structural similarity outlined above.

Claims 1,13 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Grinev (cited by applicants). The journal article describes several compound swithin the instant scope for use as psychotropics. See IV series compounds on p.95. These compounds correspond to R7 being alkyl.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier

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numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt
EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600